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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,260	04/25/2006	Henry Chiu	GNE-0273 R1	4532

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,260	CHIU ET AL.	
	Examiner	Art Unit	
	/Lorraine Spector/ Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

All non-elected claims having been cancelled, the restriction requirement is moot.

Applicant's election species of SEQ ID NO: 172 in the reply filed on 6/5/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly amended claim 17 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claim was drawn to an antibody that binds a protein at least 80% identical to SEQ ID NO: 172. As amended, claim 17 is drawn to an antibody that binds to an that binds a protein at least 80% identical to SEQ ID NO: 172. This second antibody constitutes a patentably distinct antibody, as it does not share the essential structure (epitope binding regions) or function of the originally claimed (and elected) antibodies, and therefore constitutes a patentably distinct invention. It is further noted that claim 17 as currently written would be anticipated by a plethora of prior art, though that art has not been searched (the examiner does not have the citations themselves, but is aware that anti-antibody antibodies exist in the art).

Accordingly, claim 17 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The claims are drawn to antibodies that bind SEQ ID NO: 172, encoded by SEQ ID NO: 171, and also referred to as PRO38457 cDNA and clone DNA227994.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

It is noted that at paragraph [0011] of the specification, an antibody is defined as a genus, that genus including a fragment of an antibody.

Claim Rejections - 35 USC § 101 and §112, first paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

At page 1 of the specification, it is stated that an experiment such as Example 1, found at page 94 of the specification can "reveal new genes associated with B cell activation." This is true. However, the specification goes on to speculate about unspecified diseases that might be associated with such genes, drugs that could be developed to treat such diseases, etc. While Example 1 states that PRO38457 is "significantly overexpressed" in stimulated B cells, the specification does not identify any disease or condition that could be diagnosed or treated as a result of that knowledge. Accordingly, the only use for the claimed antibodies is for further experimentation to determine the role of PRO38457 in disease, if any, or other biological activity of such that might lead to a use. Such is clearly a mere invitation to experiment to find a use for the claimed subject matter.

The instant specification lacks utility and is not enabling because one cannot, following the guidance presented therein, practice the suggested utility of diagnosing an immune disorder or screening for agents that might be used to treat such a disorder. Utility must be in readily available form. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby

was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to antibodies that bind a protein which has undetermined function or biological significance. All that has been shown is that the mRNA that encodes the protein to which the claimed antibodies bind is overexpressed in stimulated B cells. Until some actual and specific activity can be attributed to the protein identified in the specification as PRO38457 protein or a connection to a disease or medical condition established, the claimed invention is incomplete. Merely using the antibodies to isolate or assay the protein to which they bind does not constitute a patentable utility, but rather constitutes use for further experimentation to determine the significance of the protein or antibodies.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of Genentec, Inc, v. Novo Nordisk, 42 USPQ 2d 100,(CAFC 1997), the court held that:
"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

In this case the finding of *Genentec v. Novo Nordisk* is extendable to a lack of utility because applicants have presented the mere germ of the idea that PRO 38457 may be involved in an immune disorder, but have not identified any such disorder, such that there is no readily available use for the claimed antibodies.

Claims 12-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 16 is further rejected under 35 U.S.C. §112, first paragraph, as it would require undue experimentation to determine a "therapeutically effective" amount of an antibody for which no therapeutic method is described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite because to the extent that the claimed antibody may bind to the up to 20% of the protein that is *not* part of SEQ ID NO: 172, the metes and bounds of the antibody cannot be determined. Simply put, the claimed antibody could bind to almost anything, so long as the length of that anything was less than 28 residues (20% of SEQ ID NO: 172).

Claim 16 is indefinite because, in the absence of any disclosure of any condition that can be treated with the claimed antibody, the metes and bounds of a "therapeutically effective" amount cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

Priority

This application claims priority to provisional application 60/411392, filed 9/16/2002. Given the date of the prior art cited below, that priority claim has not been evaluated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6812339 (Venter et al.)

Venter et al.'s SEQ ID NO: 6789 is 100% identical, and of identical length as SEQ ID NO: 172. Antibodies, including monoclonal antibodies, are disclosed at col. 13 including monoclonal, polyclonal, fragments such as Fab or F(ab')hd2 and Fv fragments. Uses of the antibodies including methods of treatment, which would necessitate suspension in a pharmaceutically acceptable carrier, are discussed at column 36, and kits are disclosed at column 37, first paragraph. Accordingly, the claims are anticipated by Venter et al.

Claims 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7078169 (Ashby et al.)

Ashby et al.'s SEQ ID NO: 2 is 100% identical to SEQ ID NO: 172 over the entire length of Ashby's sequence, corresponding to residues 8-121 of SEQ ID NO: 172. Beginning at column 34, production of antibodies to the protein is discussed, including production of polyclonal or monoclonal antibodies (lines 62-64), single chain, and humanized (col. 35, lines 55-56). Pharmaceutical compounds are discussed at column 39. Accordingly, the claims are anticipated by Ashby et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veitia et al., Cytogenet. Cell Genet. 85:217-220, 1999 in view of U.S. Patent No. 6936691

Veitia et al. teach a partial, but substantially complete sequence that corresponds to SEQ ID NO: 172, see Figure 1B. They teach that this gene is "strongly expressed in testis and cancer cell lines" (title and figure 2), and suggest in the final paragraph of the paper that the gene is likely to be overexpressed in cancer cells, and to contribute to a high rate of cell proliferation. Veitia et al. do not teach antibodies to the protein.

U.S. Patent No. 6936691 (Fiscella et al.) teach the use of antibodies for detection and treatment of tumors. For example:

> Brief Summary Text - BSTX (99):
> The tissue distribution in testicular tissue indicates that polynucleotides and polypeptides corresponding to this gene would be useful for diagnosis, detection, prevention and/or treatment of tumors of tissues where expression has been indicated, including but not limited to testis tumors and brain tumors; in addition to disease and disorders associated with these tissues, such as infertility. Polynucleotides and polypeptides corresponding to this gene would be useful for the treatment and diagnosis of conditions concerning proper testicular function (e.g. endocrine function, sperm maturation), as well as cancer. Therefore, this gene product would be useful in the treatment of male infertility and/or impotence. This gene product is also useful in assays designed to identify binding agents, as such agents (antagonists) are useful as male contraceptive agents. Similarly, the protein is believed to be useful in the treatment and/or diagnosis of testicular cancer. The testes are also a site of active gene expression of transcripts that is expressed, particularly at low levels, in other tissues of the body. Therefore, this gene product may be expressed in other specific tissues or organs where it may play related functional roles in other processes, such as hematopoiesis, inflammation, bone formation, and kidney function, to name a few possible target indications. Moreover, the protein would be useful in the detection, treatment, and/or prevention of a variety of vascular disorders and conditions, which include, but are not limited to microvascular disease, vascular leak syndrome, aneurysm, stroke, embolism, thrombosis, coronary artery disease, arteriosclerosis, and/or atherosclerosis. Furthermore, the protein may also be used to determine biological activity, to raise antibodies, as tissue markers, to isolate cognate

> ligands or receptors, to identify agents that modulate their interactions, in addition to its use as a nutritional supplement. Protein, as well as, antibodies directed against the protein may show utility as a tumor marker and/or immunotherapy targets for the above listed tissues.

At columns 64-65 antibodies are further discussed, including monoclonal, humanized and single chain antibodies.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to make antibodies as taught by Fiscella et al. to the protein disclosed by Veitia et al. in because Veitia et al. identify the protein as being associated with cancer, and Fiscella et al. teach the utility of antibodies to proteins that are associated with cancer, including antibodies in pharmaceutically acceptable carriers, therapeutic amounts, and humanized, monoclonal and fragment antibodies. Accordingly, the invention as claimed is *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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